DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

MAY 6 2008

Re: Avastin
U.S. Patent No. 6,639,055
Docket No.: 2007E-0184

The Honorable Jon Dudas
Undersecretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Dudas:

This is in regard to the application for patent term extension for U.S. Patent No. 6,639,055, filed by Genentech, Inc., under 35 U.S.C. section 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Avastin (bevacizumab), the human biological product claimed by the patent.

The total length of the regulatory review period for Avastin is 2,551 days. Of this time, 2,401 days occurred during the testing phase and 150 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this biologic product became effective: March 5, 1997.

   The applicant claims February 3, 1997, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was March 5, 1997, which was thirty days after FDA receipt of the IND.

2. The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act: September 30, 2003.

   The applicant claims August 29, 2003, as the date the biologics license application (BLA) for Avastin (BLA 125085/0) was initially submitted. The applicant claims this is the date it submitted the first unit of BLA 125085/0, which was submitted in several units as part of a rolling application procedure. It is FDA's position that the approval phase begins when the marketing application is complete. A review of FDA records reveals that the final module of the BLA 125085/0 was submitted on September 30, 2003, which is considered to be the initially submitted date of the complete marketing application.

3. The date the application was approved: February 26, 2004.

FDA has verified the applicant's claim that BLA 125085/0 was approved on February 26, 2004.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. section 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

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